

REMARKS

The Office Action of November 20, 2003 is acknowledged. Claims 72-83 were rejected in the Office Action.

Interview Summary

Applicant thanks the Examiner for participating in a telephone interview of February 12, 2004 in which the inventors Jonathan Roth and Geoffrey Roth were in attendance. Applicant provided photographs of the inventive test medium shown indicating *E.coli*, general coliforms, *Salmonella*, and *Aeromonas*, as four separate colors that are easily detected, differentiated and quantified. The Examiner concurred that Applicant's test medium was novel and non-obvious. However, the Examiner noted concerns with the conjunctives used in some of the claims and suggested modifications, which have been incorporated in the above amendments. Furthermore, the Examiner noted that the type of substrates should be identified in claim 72 to clarify the claim and clearly differentiate from the cited prior art. Accordingly, claim 72 has been amended to identify the type of substrates in the test medium.

Claim of Priority

The Examiner requested that the specification identify Application No. 09/357,606 filed July 7, 1999 from which subject Application claims priority. An appropriate amendment has been included.

Rejections Under 35 U.S.C. § 103(a)

Claims 72-75 and 77-83 were rejected under 35 U.S.C. § 103(a) as being obvious over the combination of U.S. Patent No. 5,726,231 to *Roth et al.* in view of the article to *James et al.* entitled "Detection of Specific Bacterial Enzymes by High Contrast Metal Chelate Formation: Specific Detection of *E. coli* on Multipoint Inoculated Plates Using 8-Hydroxyquinoline-Beta-D-Glucuronide" and in further view of U.S. Patent No. 4,308,348 to *Monget*, and PCT International Patent Application WO 98/55644 to *Perry et al.* As discussed in the interview, *Roth et al.* only teaches the use of two chromogens which act on *E. coli* and coliforms. A ph-indicator not a chromogen is used to identify the *Salmonella* and *Proteus*. *Roth et al.* does not teach or suggest the use of more than two enzyme specific substrates; otherwise, he would not have had to use a ph-indicator if he thought additional substrates would work. Furthermore, *Roth et al.* does not mention the detection of *Aeromonas*.

As for *James et al.*, *James et al.* only uses Hydroxyquinoline compound to attempt to identify *E. coli*. Furthermore, *James et al.* does not mention that Hydroxyquinoline can or should

be combined with chromogens or Indoxyl compounds. Furthermore, *Aeromonas* is not mentioned or suggested in any way in the *James*' article.

In addition, the test medium and method found in *Monget* is nothing like Applicant's test medium that includes two chromogenic and one non-chromogenic substrate in a nutrient based medium for growing bacteria and wherein bacteria can easily be detected, quantified and differentiated. In *Monget*, bacteria are grown separately in a gelose medium and then placed in a microtube (column 1, lines 50-52). *Monget* discloses a test medium where a β -galactosidase and β -glucosidase are impregnated on a disk of paper contained in the microtube. Although *Monget* mentions that the test may be also conducted with other substrates, *Monget* offers no teaching on how the bacteria would be differentiated in a test medium with more than two substrates. Furthermore, *Monget* offers no teaching on the use of a non-chromogenic substrate in combination with two chromogenic substrates in the test medium or a test medium for testing for *Aeromonas*.

Perry et al. discloses a test medium using α -D-galactosidase and β -D-galactosidase substrates for identifying the presence of *Salmonella*. The β -D-galactosidase substrate is cyclohexenoescluletin, which is a non-chromogenic substrate, although *Perry et al.* identifies it as a chromogenic substrate. *Perry's* medium cannot distinguish and differentiate *E.coli*, general coliforms and *Aeromonas* as all are positive to β -D-galactosidase and all would appear as substantially black colonies. Furthermore, *Perry et al.* offers no suggestion on how the substrates could be combined with another chromogenic substrate in order to differentiate or identify additional bacteria. In addition, *Perry et al.* does not teach the use of a β -D-glucuronide substrate nor a substrate for detecting *Aeromonas*. Accordingly, using the β -D-galactoside suggested by *Perry et al.* would render the test medium in Applicant's invention nonfunctional. As such, the above remarks and distinctions in clarifying claim amendments to claims 72, 73, 76 and 79-83 should be allowable over *Roth et al.* in view of *James et al.* and in further view of *Monget* and *Perry et al.*

Claim 76 was rejected under 35 U.S.C. § 103(a) as being obvious over a combination of *Roth* in view of *James* and further view of *Monget* and *Perry* as applied to claims 72-75, and 77-83 and in further view of *Kampfer*. Applicant notes that the rejection is now moot as the reference to detecting *Shigella* in claim 76 has been eliminated in the above amendment.

Claims 81-83 were rejected as being unpatentable over PCT International Publication No. WO 96/40980 to *Townsend et al.* in view of *Monget*. Applicant acknowledges that *Townsend et al.* mentions the detection of numerous bacteria including *Aeromonas* and also lists a multitude of various substrates in Table 1. As discussed in the interview; however, *Townsend et al.* does not teach a method for detecting, quantifying or differentiating colonies of *Aeromonas* from other biological entities in a test sample. Although *Townsend et al.* mentions *Aeromonas*, he offers no explanation or teaching how *Aeromonas* should be quantified or differentiated from other bacteria.

Furthermore, *Townsend et al.* fails to teach the test medium used in the claimed method including a β -D-galactoside, α -D-galactoside and a β -D-glucuronide. Furthermore, in particular, claim 1 includes the method for detecting or differentiating *Aeromonas*, *Salmonella* and general coliforms. *Townsend et al.*, however, is directed towards merely quantifying the total number of viable bacteria present in ground beef and chicken (page 14, lines 21-23 and page 15, 19-22).

As discussed in the interview and above, *Monget* adds nothing to cure the lack of teachings in *Townsend et al.* regarding the subject method and test medium.

Claim Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 72-83 were rejected as being non-enabling for other non-chromogenic substrates besides hydroxyquinoline- β -D-glucuronide. Applicant respectfully disagrees with this assertion as the use of other non-chromogenic substrates are specified in the specification on page 28, lines 11-17 and in Table V.

The Examiner also asserted that the three substrates required in the medium of the claims were not defined in the claims in a manner, which would permit one skilled in the art to make and use the invention. The substrates of the medium have been further defined and clarified in the attached amendments.

The Examiner also asserted that the claims are not enabled for distinguishing *Shigella* from *E. coli*. Applicant notes that this rejection is moot as the references to *Shigella* in claims 76 and 83 have been eliminated.

The Examiner also asserted that the specification is enabling for a method to detect and distinguish *E. coli*, coliforms and *Salmonella*, but does not reasonably provide an enablement for similar medium for detecting and distinguishing *E. coli*, coliforms and *Aeromonas*. As discussed in the interview and demonstrated in the photographs provided to the Examiner, Applicant's medium clearly provides a way of detecting and distinguishing *E. coli*, coliforms, *Aeromonas* and *Salmonella*. The photographs provided to the Examiner demonstrate the use of one example of the test medium as described on page 20, lines 20-25 in the Application. With this medium, *E.coli* shows as a substantially black color, general coliforms as a blue-violet color, *Aeromonas* as a pink color and *Salmonella* as a teal color as described on page 22, lines 14-31 and page 23, lines 1-8 of the specification. The Examiner is correct that *Aeromonas* does not produce β -glucuronide; however, as indicated in the specification on page 22, lines 26-31, *Aeromonas* is β -galactosidase positive, providing the pink color associated with 6-chloro-3-indolyl- β -D-galactoside.

Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

Claim 74 was rejected for the redundant use of "one of". Applicant notes that this rejection is moot based on the cancellation of claim 74.

Claim 76 was rejected based on the assertion that "substantially nondefusable" is not defined by the claim or specification. Applicant respectfully traverses this rejection as the Examiner is aware the term "substantially" has been found to be definite as one of ordinary skill in the art knows what terms such as "substantially equal" mean. MPEP § 2173.05(b)(D).

The Examiner also objected that the title of the invention is not aptly descriptive. Accordingly, Applicant has provided a new title in the attached amendment.

Having fully responded to the Office Action, Applicant respectfully requests that remaining claims 72, 73, 76, and 79-83 be allowed. Applicant notes that certain claims have been amended and/or cancelled solely to advance prosecution of this Application and to obtain allowance on clearly allowable claims at the earliest possible date. Therefore, no admission may be inferred by the cancellations and amendments to the claims herein. Should the Examiner have any further questions or comments, he is invited to call the undersigned representative of the Applicant.

Respectfully submitted,



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